510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K031798

B. Analyte:
Human chorionic gonadotropin

C. Type of Test:
Qualitative

D. Applicant:
Standard Diagnostics, Inc.

E. Proprietary and Established Names:
Good Morning Test

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155
2. Classification:
   Class II
3. Product Code:
   LCX
4. Panel:
   75

G. Intended Use:

1. Intended use(s):
   The Good Morning Test kit is a qualitative chromatographic immunoassay, which determines whether a woman is pregnant or not by identifying the presence of hCG in urine.
2. Indication(s) for use:
   The Good Morning Test kit is a qualitative chromatographic immunoassay, which determines whether a woman is pregnant or not by identifying the presence of hCG in urine.
3. Special condition for use statement(s):
   This device is intended for over-the-counter use.
4. Special instrument Requirements:
   Not applicable

H. Device Description:
The test kit consists of 1 test device individually foil pouched and instructions for use. The test device contains mouse anti-beta hCG monoclonal antibody/colloidal gold, goat anti-hCG (test line), and goat anti-mouse IgG (control line).

I. Substantial Equivalence Information:

1. Predicate device name(s):
   First Response 1-Step Pregnancy Test, Applied Biotech Surestep
2. Predicate K number(s):
   K030258, K921170

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicates**
Intended Use	Detects hCG in urine, for early detection of pregnancy, for OTC use	Detects hCG in urine, for early detection of pregnancy, for OTC use
Principle	Chromatographic immunoassay	Chromatographic immunoassay
Differences		
Item	**Device**	**Predicate**
Day of use	First day of a missed period	First Response can be used *before* a missed period

J. Standard/Guidance Document Referenced (if applicable):
Not applicable

K. Test Principle:
The test is an immunochromatographic assay.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Within-run, between-run, batch to batch, and lab to lab performance were evaluated using blind labeled, negative and positive urine samples spiked with hCG (WHO 3rd I.S.). To evaluate within-run performance, an analyst tested 0, 25, 250 and 500 mIU/mL samples ten times each. To evaluate between-run performance, three different analysts tested 0, 25, 250, and 500 mIU/mL samples three times each. To evaluate batch to batch performance, one analyst tested 0, 25, 250, and 500 mIU/mL samples three times each with three different batches. To evaluate lab to lab performance, one analyst at three different labs tested 0, 25, 250, and 500 mIU/mL samples three times each. The results from all four studies were in 100% agreement with the expected results.

b. Linearity/assay reportable range:
Not applicable

c. Traceability (controls, calibrators, or method):
WHO 3rd International Standard (I.S.)

d. Detection limit:
Sensitivity was evaluated by spiking thirty-three (33) clinical samples from normal, non pregnant females with six (6) different concentrations of hCG (WHO 3rd I.S.): 100 mIU/mL, 50 mIU/mL, 25 mIU/mL, 18.75 mIU/mL, 12.5 mIU/mL, and 0 mIU/mL. The thirty-three (33) samples consisted of 10 each at 25, 50, and 100 mIU/mL concentrations; and 1 each at 0, 12.5, and 18.75 mIU/mL

concentrations. All the samples at 25 mIU/mL and above were positive, and all samples at 18.75 and below were negative.

e. Analytical specificity:
Homologous hormones (1000 mIU/mL FSH, 500 mIU/mL LH, and 1000 μIU/mL TSH), drugs, and urinary analytes were evaluated for potential interference. Drugs and urinary analytes were added to urine samples containing 0 and 50 mIU/mL hCG. No cross reactivity was observed for any of the negative or positive samples containing the elevated concentrations of potential interferents.

f. Assay cut-off:
See Detection limit above.

2. Comparison studies:
   a. Method comparison with predicate device:
   Randomly selected pregnant urine (150) and non-pregnant urine (145) samples were analyzed by the Good Morning Test in parallel with a commercially available qualitative visual hCG test. The pregnant urine specimens were composed of various weeks of pregnancy, ranging from 3 to greater than 13 weeks. The results showed 100% agreement between the two methods for all samples.
   b. Matrix comparison:
   Not applicable
3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b are not applicable):
   One hundred and ten (110) layer persons performed self-testing using the Good Morning Test at a hospital to determine whether or not they were pregnant. They performed the tests unassisted, following instructions provided in the labeling. The patient also underwent an ultrasound examination and had their samples analyzed by a professional using a commercially available method. The results by all three methods were in complete agreement, with fifteen (15) being negative and ninety-five (95) being positive.
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   This has been established in the literature.

M. Conclusion:

The intended use, test principle, and performance data were similar between the subject device and its two predicates. Additionally, the revised labeling is adequate and similar to labeling of commercially available OTC pregnancy tests. Therefore, I recommend a substantial equivalence determination for the Good Morning Test.